

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P. and)
TCD ROYALTY SUB LP,)
)
Plaintiffs,)
)
v.) C.A. No.: 22-1312 (SB)
)
ALEMBIC PHARMACEUTICALS LIMITED)
and ALEMBIC PHARMACEUTICALS, INC.,)
)
Defendants.)

SCEDULING ORDER

This 13th day of March 2023, the Court having waived a Case Management Conference/Rule 16 scheduling and planning conference pursuant to Local Rule 16.1(a), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) by **March 17, 2023**.
2. E-Discovery Default Standard. Unless otherwise agreed to by the parties, the parties shall make their ESI Initial Disclosures pursuant to Paragraph 3 of the Court's Default Standards for Discovery, Including Discovery of Electronically Stored Information ("ESI") by **March 24, 2023**. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including

Discovery of Electronically Stored Information (“ESI”) (which is posted at <https://www.ded.uscourts.gov/default-standard-discovery>, and is hereby incorporated herein by reference).

The parties will negotiate in good faith to reach an agreement regarding modifications to the Court’s Default Standard for Discovery, Including Discovery of Electronically Stored Information (“ESI”), and the parties will submit the agreed modifications, if any, to the Court, by

March 27, 2023.

3. Joinder of Other Parties and Amendment of Pleadings. All motion to join other parties, and to amend or supplement the pleadings, shall be filed on or before **September 1, 2023.**

4. Discovery. Unless otherwise ordered by the Court, the limitations on discovery set forth in Local Rule 26.1 shall be strictly observed.

a. Identification of Asserted Patents and Accused Products. By **April 14, 2023** and for each defendant, the plaintiffs shall specifically identify the accused product(s) and the asserted patent(s) they allegedly infringe, and produce the file history for each asserted patent.

b. Production of Core Technical Documents. By **April 21, 2023**, the defendants shall produce to each plaintiff the core technical documents related to the accused product, including but not limited to defendants’ Abbreviated New Drug Application (“ANDA”) No. 216631 and all amendments, supplements, and correspondence between Defendants and the United States Food and Drug Administration (“FDA”) related thereto; operation manuals; product literature; schematics; and specifications.

c. Plaintiffs' Initial Related Litigation Production. By **April 21, 2023**, the Plaintiffs shall produce to Defendants any documents that were originally produced in any of the actions captioned *Research Foundation of State University of New York, et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 09-184 (D. Del.), *Mylan Pharmaceuticals Inc. v. Galderma Laboratories Inc., et al.*, C.A. No. 10-892 (D. Del.), *Galderma Laboratories Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 11-1106 (D. Del.), *Galderma Laboratories, L.P. et al. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 16-207 (D. Del.), *Galderma Laboratories, L.P. et al. v. Sun Pharmaceutical Industries Limited et al.*, C.A. No. 16-1003 (D. Del.), *Galderma Laboratories, L.P. et al. v. Sun Pharmaceutical Industries Limited et al.*, C.A. No. 18-1588 (D. Del.), *Galderma Laboratories, L.P. et al. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 19-440 (D. Del.), and *Galderma Laboratories Inc. et al. v. Lupin Inc. et al.*, C.A. No. 21-1710 (D. Del.). The parties may produce such documents as they were originally produced, i.e., as single page TIFF images and associated multi-page text files containing OCR with appropriate load files, without extracted text or metadata.]

d. Initial Infringement Claim Charts. By **May 12, 2023**, the plaintiffs shall produce to each defendant an initial claim chart relating each accused product to the asserted claims each product allegedly infringes.

e. Initial Invalidity Contentions. By **May 26, 2023**, the defendants shall produce to each plaintiff an initial disclosure of invalidity contentions relating to each of the asserted claims.

f. Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **November 3, 2024**.

g. Document Production. Document production has already begun and shall be substantially complete by **September 1, 2023**.

h. Requests for Admission. A maximum of 50 requests for admissions are permitted for each side. Requests for Admission directed to authenticity or admissibility of documents, however, will not count toward this maximum.

i. Interrogatories.

i. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides, *i.e.*, the more detail a party provides, the more detail a party shall receive.

j. Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination.

ii. Location of Depositions. The parties will confer in an attempt to identify mutually agreed locations for depositions. In general, depositions of Plaintiffs' witnesses who reside in the United States will occur in the Cahill Gordon & Reindel offices in New York,

NY, or at a location in the United States convenient for the witness, and depositions of Defendants' witnesses who reside in the United States will occur in the offices of Sterne, Kessler, Goldstein & Fox P.L.L.C. in Washington, DC, or at a location in the United States convenient for the witness. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. The parties agree to meet and confer regarding the location of depositions and whether any deposition shall be conducted by remote means (*e.g.*, Zoom or other similar means) in view of convenience of the witness, health reasons, or travel-related restrictions due to the COVID-19 pandemic. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purposes of this provision.

k. Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before **December 8, 2023**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **January 12, 2024**. Reply expert reports from the party with the initial burden of proof are due on or before **February 9, 2024**. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Expert Depositions. The parties agree that all expert depositions will be conducted on or before **March 1, 2024**.

iii. Expert Report Supplementation. The parties agree they will permit expert declarations to be filed in connection with motions briefing.

iv. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion by **March 15, 2024**, unless otherwise ordered by the Court. Briefing shall be pursuant to the District of Delaware Local Rules.

1. Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts—including oral communication among Delaware and Lead Counsel for all parties to the dispute—that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

Dear Judge Bibas:

The parties in the above-referenced matter write to request the scheduling of a discovery teleconference. The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on [INSERT DATES].

The disputes requiring judicial attention are listed below:

[A NON-ARGUMENTATIVE LIST OF DISPUTES REQUIRING JUDICIAL ATTENTION]

- iii. One week after the filing of the joint letter, the party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. Within three days, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's reasons for its opposition.
- iv. In its discretion, the Court will schedule a teleconference to hear arguments on the dispute.

5. Motions to Amend.

a. Any motion to amend (including a motion for leave to amend) a pleading shall *NOT* be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a "blackline" comparison to the prior pleading.

b. Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

c. Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

6. Motions to Strike.

a. Any motion to strike any pleading or other document shall *NOT* be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

b. Within seven (7) days after the filing of a motion in compliance with his Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

c. Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

7. Application to Court for Protective Order. The parties shall file a proposed Protective Order with this Court on or before **March 27, 2023**. Should a dispute arise concerning that Protective Order, counsel must follow the provisions of Paragraph 4(k) above.

The Stipulated Protective Order includes the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

8. Papers Filed Under Seal. A redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document. Administrative Procedures Governing Filing and Service by Electronic Means § G.

9. Courtesy Copies. The parties need not provide to the Court any courtesy copies of briefs, any other document filed in support of any briefs (such as appendices, exhibits, declarations, and affidavits), or papers filed under seal.

10. ADR Process. After the filing of case dispositive motions, this matter may be referred to a magistrate judge to explore the possibility of alternative dispute resolution.

11. Tutorial Describing the Technology and Matters at Issue. Unless otherwise ordered by the Court, the parties may optionally provide the Court, no later than the date on which the Joint Claim Construction Brief is due, a tutorial on the technology at issue. In that regard, the parties may separately or jointly submit a DVD of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and should not be used for argument. The parties may choose to file their tutorial(s) under seal, subject to any protective order in effect. Each party may comment, in writing (in no more than five (5) pages) on the opposing party's tutorial. Any such comment shall be filed no later than one week after the date on which the Joint Claim Construction Brief is due. As to the format selected, the parties should confirm the Court's technical abilities to access the information contained in the tutorial.

12. Claim Construction Issue Identification. On **June 2, 2023**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be submitted on **June 9**. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. The parties' Joint Claim Construction Chart shall also identify any expert witness a party may rely upon, and a summary of the witness' anticipated testimony. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall

not provide argument. The parties are instructed to meet and confer three days prior to the submission of the Joint Claim Chart to discuss whether prior Markman decisions dispose of any term(s)/phrase(s) of the claim(s) in issue.

13. Claim Construction Briefing. The Plaintiff shall serve, but not file its opening brief, not to exceed 20 pages, on **June 23, 2023**. The Defendants shall serve, but not file, their answering brief, not to exceed 30 pages, on **July 7, 2023**. Plaintiffs shall serve, but not file, their reply brief, not to exceed 20 pages, on **July 21, 2023**. Defendants shall serve, but not file, their sur-reply brief, not to exceed 10 pages, on **August 4, 2023**. No later than **August 9, 2023**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-upon Constructions

II. Disputed Constructions

A. [TERM 1]

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

B. [TERM 2]

1. Plaintiffs' Opening Position

2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix. Citations to intrinsic evidence shall be set forth in the Joint Claim Construction Brief. Citations to expert declarations and other extrinsic evidence may be made in the Joint Claim Construction Brief as the parties deem necessary, but the Court will review such extrinsic evidence only if the Court is unable to construe the disputed claim terms based on the intrinsic evidence.

14. Expert Depositions Regarding Claim Construction. The parties shall conduct any expert depositions related to claim construction by **August 23, 2023.**

15. Hearing on Claim Construction. **At the Court's Convenience**, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

16. Interim Status Report. On **September 29, 2023**, counsel shall submit a joint letter to the Court with an interim report on the nature of the matters in issue and the progress of discovery to date. Then, if the Court deems it necessary, it will schedule a status conference.

17. Supplementation. Absent agreement among the parties, and approval of the Court, no later than **November 10, 2023**, Plaintiffs must finally supplement, *inter alia*, the identification of all accused products and infringement contentions. Absent agreement among the parties, and approval of the Court, no later than **November 10, 2023**, the Defendants must finally supplement, *inter alia*, the invalidity references and invalidity contentions.

18. Case Dispositive Motions. Absent leave of the Court, the parties will not file any case dispositive motions in this case.

19. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

20. Duplicates. The parties should not submit duplicates of the same document. If a party attaches a document as an exhibit to a motion, the opposing party should cite to that exhibit, rather than attaching a new exhibit of the same document to his own motion.

21. Pretrial Conference. **At the Court's convenience**, the Court will hold a pretrial conference. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial

disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order on or before **April 19, 2024**. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) (1)(3) for the preparation of the joint proposed final pretrial order. The Court will advise the parties at or before the above-scheduled pretrial conference whether an additional pretrial conference will be necessary.

22. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each *SIDE* shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument and may be opposed by a maximum of three (3) pages of argument, and the party making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

23. Trial. This matter is scheduled for a four (4) day bench trial beginning **at the Court's convenience**. Trial days will end no later than 5:00 p.m. each day.

² Plaintiffs disagree with Defendants' alternate dates for trial and are happy to discuss it more at a scheduling conference should the Court request one.

³ The 30-month stay expires on Feb. 23, 2025. To the extent the Court denies Defendants' request for an expedited trial, Defendants respectfully request a trial by July/August 2024 so that the Court has sufficient time to issue its decision before the expiration of the 30-month stay.

The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

24. Post-Trial Briefing. The parties will address the post-trial briefing schedule and page limits in the proposed final pretrial order.

SO ORDERED this 13th day of March 2023.



The Honorable Stephanos Bibas,
U.S. Court of Appeals for the Third Circuit